PrescQIPP Community Interest Company

Oxycodone/naloxone (Targinact®)

This is one of a number of bulletins providing further information on medicines that should be given low priority, are poor value for money, are suitable for self care or for which there are safer, more suitable alternatives. This guidance will support Clinical Commissioning Groups (CCGs) in taking action on items that should not routinely be prescribed in primary care or on the NHS. Further bulletins, including the overarching low value medicines information bulletin are available on the PrescQIPP website: https://www.prescqipp.info/drop-list/headline-areas/the-prescqipp-drop-list#low-value-medicines-lvm

This bulletin focuses on oxycodone/naloxone prolonged release (PR) (Targinact®) tablets and provides the rationale for therapy to be stopped, for patients to be switched to alternative agents and for new patients not to be started on Targinact® tablets. This project should be used in conjunction with the PrescQIPP project on non-neuropathic pain and oxycodone resources.

Recommendations

- Commence new patients requiring strong opioid therapy on morphine sulfate. Oxycodone can be considered as an option in patients who are intolerant of morphine sulfate, i.e. develop unacceptable side effects when taking morphine even when adjunct treatment is added to reduce these side effects or in renal impairment.[1]
- When initiating opioids, always consider a one to two week opioid trial (or long enough to observe the effect of opioids on two or three episodes of increased pain) to establish if the patient achieves a reduction in pain intensity and ability to achieve specific functional improvements (including sleep).[2] See PrescQIPP project on non-neuropathic pain.
- Review all patients currently on Targinact® tablets for suitability for switching to morphine sulfate. Switch all suitable patients to an appropriate formulation of morphine sulfate. As with all switches, these should be tailored to the individual patient. Prescribers should be aware of the difference in potency of oxycodone compared to morphine (morphine dose is 1.5 to 2 times oxycodone dose).
- Review all patients that need to be switched to an equivalent daily dose of 120mg oral morphine equivalent. Increasing opioid load above this dose is unlikely to yield further benefits but exposes the patient to increased harm. Consider specialist review.[2]
- When switching to morphine sulfate, ensure additional concomitant regular laxative therapy, for example a combination of stool-softening and stimulant laxatives (e.g. in terminal illness - docusate plus senna or bisacodyl, or co-danthramer; or lactulose plus bisacodyl or senna in those not terminally ill). Please note it may not be appropriate to switch oxycodone in terminally ill patients.
- As with all switches, the dose should be tailored to the individual patient. Prescribers should be aware of the difference in potency of oxycodone compared to morphine.
- Patients on Targinact® unsuitable for a switch to morphine sulfate should be switched to an equivalent dose of oxycodone PR, prescribed as a cost effective brand, e.g. Longtec®.[3] CCGs should take into account the strengths and manufacturer availability.
- To avoid confusion between the prolonged release products and standard release oxycodone products, all prolonged release oxycodone should be prescribed by brand.

- Patients on long term opioid therapy for non-cancer pain should be reviewed regularly to assess whether there is a continued need for treatment with an opioid.
- Prescribers should be aware of the abuse potential of all opioids and careful consideration should be given when prescribing opioids for non-cancer pain to patients with a history of substance misuse or where abuse is a concern. Refer patients with a history of addiction involving opioids or other drugs to specialist services with expertise in pain medicine and addiction management.[2]

Background

The NHS England guidance on items which should not routinely be prescribed in primary care lists products that are regarded as low priority for funding, poor value for money or for which there are safer alternatives (https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/). Oxycodone/naloxone prolonged release (Targinact®) features on the list as an item that is poor value for money, as although it is clinically effective, more cost-effective products are available.

National guidance

The National Institute of Health and Care Excellence (NICE) clinical guideline 140 on the safe and appropriate prescribing of strong opioids for pain in adults with advanced and progressive disease was reviewed in July 2016 and found no major changes that would affect the recommendations over the next three to five years.[1]

The guideline recommends morphine sulfate as the first line oral opioid of choice when initiating treatment and sustained release morphine sulfate as the strong oral opioid of choice for maintenance treatment. It also recommends that laxatives and/or antiemetic treatments are prescribed and optimised before considering changing oral opioid therapy. For patients experiencing drowsiness from therapy, NICE recommends either:

1. Reducing the treatment dose if pain is controlled or
2. Switching the opioid if pain is not controlled.[1]

There is no advice from NICE on the use of strong opioids for long term pain that is outside of palliative care.

The Scottish Intercollegiate Guidelines Network (SIGN) produced a guideline on the treatment of chronic pain in 2014 which states: “there is no clear evidence that any particular opioid including morphine is better than any other in terms of efficacy for pain relief although patients were more likely to discontinue buprenorphine than morphine because of lack of effect”.[4]

The Scottish Medicines Consortium (SMC) has accepted oxycodone prolonged release (OxyContin®) for restricted use within NHS Scotland for the treatment of severe non-malignant pain requiring a strong opioid analgesic only when controlled release morphine sulfate is ineffective or not tolerated.[5]

The British Pain Society’s good practice guide for opioids for persistent pain states:

“There is evidence from clinical trials that opioids can be effective, in the short and medium term, in providing symptomatic improvement in a variety of non-cancer pain conditions. However, the safety and efficacy of opioids in the long term is uncertain as is the propensity for these drugs to cause problems of tolerance, dependence and addiction. The benefits of opioid treatment for the patient must be balanced against burdens of long term use as therapy for persistent pain may need to be continued for months or years. The position of opioid treatment must also be considered within a wider social context and issues such as diversion must be addressed”.[6]

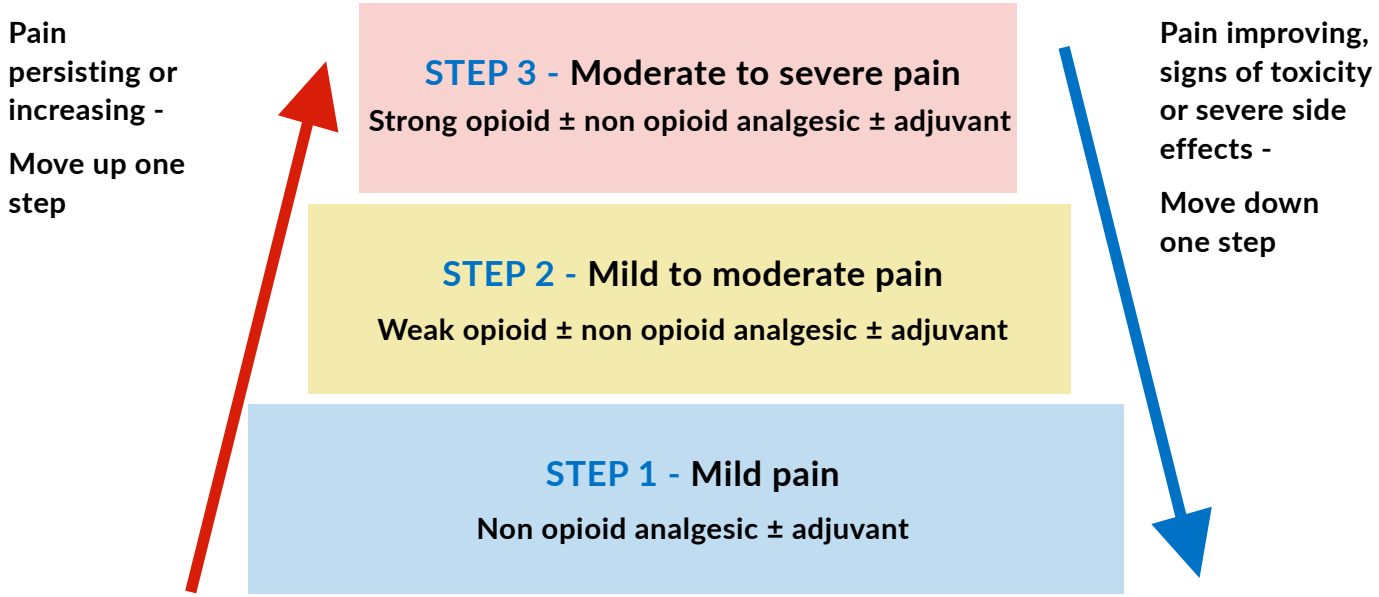
Clinical evidence

There is little evidence that one opioid is more effective and associated with fewer side effects than another. Non-morphine opioids, such as fentanyl, buprenorphine and oxycodone are significantly more expensive than oral morphine. There is no consistent evidence to suggest that non-morphine opioids are any more effective, or show improved tolerability when compared with oral morphine.[2,6,7] Oral morphine should be the drug of first choice. However, there is a theoretical rationale for trying an alternative opioid if the first drug that is taken is helpful but causes intolerable side effects.[2,6]

Strong opioids should only be initiated in patients after non-opioid analgesics and mild opioid analgesics have been tried. This is particularly important in patients with non-cancer pain where careful consideration should be given before prescribing strong opioids.[1]

A stepwise approach to pain management in line with the World Health Organisation (WHO) recommendations should be adopted as this minimises the risk of respiratory depression and other adverse effects in opioid naïve patients. However, there have been criticisms to this approach, including that it does not address acute or persistent pain.[2,4,8]

Diagram 1, is an adaptation of WHO pain ladder. Although this was originally developed as a resource for cancer pain, it is regularly used in non-cancer pain.



When a strong opioid is considered an appropriate treatment, morphine sulfate is widely considered as the first line strong opioid of choice. Patients are normally initiated with treatment on the immediate release formulations (given as a 4-6 hourly dose). Once their pain is controlled and the dose stabilised, the opioid can be converted to a twice-a-day sustained release formulation.[1,2,7]

Targinact® tablets contain oxycodone and naloxone and are licensed for severe pain which can be adequately managed only with opioid analgesics.[9] The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut. Naloxone is also used intravenously to reverse the effects of acute opioid overdose.

Constipation is one of the most common adverse effects from opioids; unlike some other adverse effects, tolerance does not develop with long term use. All patients prescribed regular long term strong opioids should also be prescribed regular laxatives.[7]

The NICE Clinical Knowledge Summaries (CKS) on constipation and managing pain in palliative cancer care recommend that when introducing an opioid, a stimulant laxative (such as bisacodyl, senna or danthron-containing laxative for the terminally ill) and a softening laxative (such as docusate) should be prescribed at the time of first prescription.[10, 11] A laxative with both properties (for example, co-danthramer or co-danthrusate) is also an option in terminally ill patients. The patient should also be

advised of the risks of constipation, and an adequate fluid and dietary intake (including fruit juice and fruit specifically) should be encouraged. For patients who are not terminally ill, lactulose plus bisacodyl or senna is the preferred option.[11]

There have been a number of studies which have assessed the efficacy and safety of oxycodone/naloxone PR tablets compared to placebo.

There are only three phase III double blind, randomized controlled trials which have compared oxycodone/naloxone PR tablets with oxycodone PR tablets in patients with moderate-to-severe non-cancer pain.[12-16] All three of these studies lasted 12 weeks and all found analgesia was similar between oxycodone/naloxone PR tablets and oxycodone PR tablets.[14-16]

Two of the studies had a similar design and were assessing opioid induced constipation with oxycodone/naloxone PR compared to oxycodone PR alone. In these studies, the primary outcome was patients' assessment of their symptoms of constipation as measured by the Bowel Function Index (BFI).[14,16] In both studies, the BFI improved with oxycodone/naloxone PR tablets statistically significantly more than with oxycodone PR. In one study, after four weeks 30% of patients receiving oxycodone/naloxone PR tablets required laxatives compared with 54% taking oxycodone. Patients in the oxycodone/naloxone PR group needed to take significantly fewer laxative tablets compared with those in the oxycodone PR group ($p<0.0001$).[14] In the second of these studies significantly fewer patients taking oxycodone/naloxone PR tablets took laxatives compared to those taking oxycodone PR alone. In the oxycodone/naloxone PR treated group only 43.1% (56 out of 130) of patients took laxatives at any point during the 12-week trial, whereas in the oxycodone PR group 63.7% (86 out of 135; $p=0.0009$) of patients took laxatives.[16]

The laxative rescue protocol used was bisacodyl (not to exceed five doses of bisacodyl 10 mg/day within seven consecutive days) which is a stimulant laxative, rather than the recommended regular prophylactic use of a stimulant laxative plus a faecal softener.[14,16]

A further long term observational non-blinded follow-up of the first two studies evaluated the effects of oxycodone/naloxone PR tablets for a further 52 weeks after the end of the initial study phase. Analgesia control and use of laxatives remained constant throughout the 12 months.[17]

A further study of 185 patients with cancer pain compared oxycodone/naloxone PR tablets against oxycodone.[18] As in the previously discussed studies, this four week study used bisacodyl only as rescue therapy. After four weeks, the mean Bowel Function Index score was significantly lower with oxycodone/naloxone PR tablets; mean total laxative intake was 20% lower with oxycodone/naloxone PR tablets. Mean brief pain inventory scores were similar for both treatments.[18]

A randomized, controlled, open-label, phase 3b/4 study of non–opioid-pretreated patients with severe chronic low back pain with a neuropathic pain component, demonstrated that tapentadol PR was non-inferior to oxycodone/naloxone PR. Tapentadol PR was associated with significantly greater improvements in neuropathic pain-related symptoms and global health status than oxycodone/naloxone PR and with a significantly better gastrointestinal tolerability profile.[19]

There are no published randomised controlled trials comparing oxycodone/naloxone PR tablets against oral morphine given with a recommended laxative regimen of regular stool-softening and stimulant laxatives.

The Drug and Therapeutics Bulletin[12] could see no reason why Targinact® tablets should be prescribed given:

- The limitations of the trials.
- The lack of data to show that Targinact® reduces or eliminates the need for laxatives in the long term.
- The cost differential against other opioids.

The SMC did not recommend the use of Targinact® tablets in NHS Scotland due to uncertain clinical benefit and an insufficiently robust economic analysis. Oxycodone prolonged release is restricted in NHS Scotland to use in patients in whom controlled release morphine sulfate is ineffective or not tolerated.[20]

Safety of Targinact®

In two of the randomised controlled trials, the overall incidence of adverse effects with oxycodone/naloxone PR tablets was similar to oxycodone PR and adverse effects were as expected with any strong opioid.[14,15] In one study, the overall incidence of adverse effects was higher with oxycodone/naloxone PR tablets than with oxycodone PR (63.1% vs. 52.6%, p value not stated).[16]

Targinact® tablets are contra-indicated in patients with moderate or severe hepatic impairment.[9] Plasma concentrations of both oxycodone, and particularly naloxone, are elevated in patients with hepatic impairment. The clinical significance of a raised naloxone plasma concentration is not clear but there is a theoretical risk that accumulation of unmetabolised naloxone could cause reversal of opioid analgesia.[21] In addition, Targinact® tablets should be used with caution in patients with mild hepatic impairment and in patients with renal impairment for the same reason.[9] The maximum recommended dose of Targinact® is 160mg oxycodone/80mg naloxone daily. The maximum daily dose is reserved for patients who have previously been maintained on a stable daily dose and who have become in need of an increased dose.[9]

For patients requiring a higher dose of analgesia, administration of supplemental opioid therapy would be required. If supplemental opioids are given, the effect of naloxone on bowel function may be impaired. The summary of product characteristics (SPC) also states that after complete discontinuation of therapy with Targinact® tablets and a subsequent switch to another opioid, a worsening of bowel function can be expected.[9]

Conversions

There is a significant difference in cost between morphine sulfate MR products and Targinact® tablets. There is also a difference in cost between Targinact® tablets and oxycodone PR (prescribed as Longtec®). Table 1 below illustrates the cost differences between different brands of morphine sulfate MR and oxycodone PR. To aid comparison the oxycodone is placed at half the morphine sulfate dose, however it could also be two thirds of the dose.

Chart 1, page 7, illustrates the cost differences between Targinact® tablets at a dose of 30mg oxycodone/15mg naloxone twice a day, oxycodone PR 30mg twice a day and different brands of morphine sulfate MR. Morphine sulfate has been shown at a dose range of 45mg/50mg (yellow bar) - 60mg (blue bar) twice daily, to illustrate the differing recommended dose conversion ratios: 30mg twice daily oxycodone is equivalent to 45mg morphine twice daily using the BNF conversion or 60mg morphine twice daily, using the Oxycontin® SPC conversion. There would also be the additional costs of laxatives illustrated in table 2 (if not already prescribed), however these would be offset by the

savings made.

Table 1: Comparison of oxycodone PR with oxycodone/naloxone PR and morphine MR[3,7]

Morphine sulfate modified release 28 day cost Dose: One tablet or capsule twice daily – least costly brand stated			**Oxycodone prolonged release 28 day cost Dose: One tablet or capsule twice daily – least costly brand stated**			**Oxycodone/naloxone prolonged release 28 day cost Dose: One tablet twice daily**	
Morphine sulfate strength	Generic tablets/ MST® Continus tablets	Generic capsules/ Zomorph® capsules	Equivalent strength to morphine (2:1)	Oxycontin®	Longtec®	Equivalent strength to morphine (2:1)	Targinact®
5mg	£3.07						
10mg	£5.04	£3.24	5mg	£25.04	£12.52	5mg/2.5mg	£42.32
15mg	£8.49						
			10mg	£25.04	£12.52	10mg/5mg	£42.32
30mg	£11.64	£7.75	15mg	£38.12	£19.06		
			20mg	£50.08	£25.04	20mg/10mg	£84.62
60mg	£22.70	£15.12	30mg	£76.23	£38.11		
			40mg	£100.19	£50.09	40mg/20mg	£169.28
			60mg	£152.49	£76.24		
100mg	£35.93	£20.35					
			80mg	£200.39	£100.19		
200mg	£75.92	£40.69					

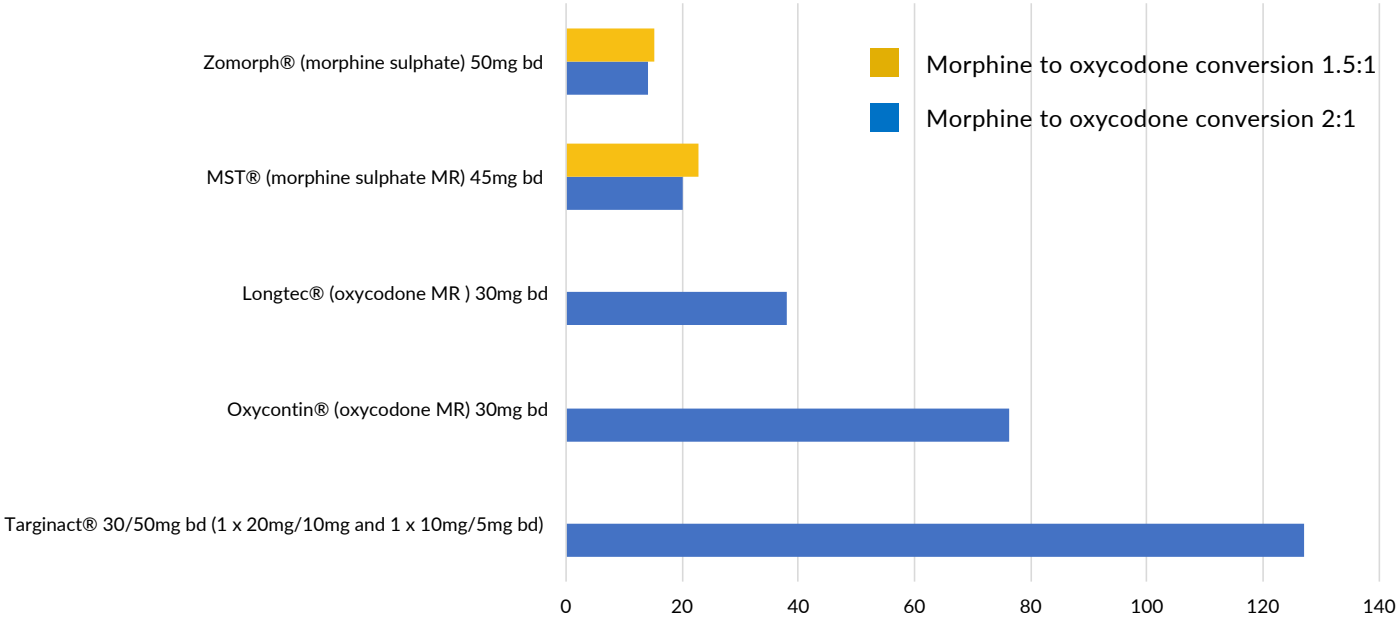
Laxatives

Table 2: Cost of laxatives

Laxative	**Cost/28 days[3]**
Bisacodyl 10mg at night	£1.83
Lactulose 15ml twice daily	£4.38
Senna 15mg at night	£1.86

199. Oxycodone/naloxone (Targinact®) prescribing 2.0

Co-danthrusate 50/60 three at night	£70



Switching options and savings available

In England and Wales, almost £4.5 million pounds is spent annually on oxycodone/naloxone PR products. There are several potential switch/review options for Targinact® products (although clinicians may choose other options according to the clinical need of the patient).

These include:

- Targinact® to morphine sulfate MR
  - For patients that have not previously tried morphine sulfate, switching all oxycodone PR product prescriptions to morphine sulfate modified release 12 hourly tablets or capsules (Zomorph® capsules is the least costly product, MST Continus® is the most commonly prescribed tablet) **could save up to £3.5 million per year. This equates to £6,058 per 100,000 patients** across the PrescQIPP membership.
  - Switch doses will need to be agreed locally between GPs, medicines management teams and pain specialists. It is advisable to use a lower dose ratio for the switch (morphine sulfate modified release at 1.5 times the oxycodone PR dose) and add morphine sulfate oral solution for breakthrough pain if needed. The dose of morphine sulfate can then be titrated up after review. Palliative care patients should not be switched.
  - Additional costs of laxatives or antiemetics (if needed and not already prescribed) would be minimal and offset against these savings.
- Targinact® to branded generic oxycodone, e.g. Longtec®
  - For patients where morphine sulfate would not be suitable, consider a switch where appropriate to an equivalent or appropriate dose of branded generic oxycodone, e.g. Longtec® (branded oxycodone modified release).
  - **Total annual savings for Targinact® to Longtec® are £2.8 million which equates to £4,971 per 100,000 patients.**

CCGs should consider the strengths of formulations available and product availability when deciding on which formulation to use.

Review

If at review the prescribing of an opioid analgesic is no longer appropriate, then therapy should be tapered down and then discontinued. Non-opioid analgesia may be appropriate in some patients. Higher doses of oxycodone/naloxone PR (up to 160mg oxycodone/80mg naloxone)are very expensive and on an individual patient basis can cost over £8,000 per year. These patients should be reviewed and attempts made to reduce their daily dose of opioids if possible (consider specialist support).

The savings above illustrate the maximum savings available. In reality, the total amount may not be achieved as different options will be suitable for different patients. The data pack shows prescribing data at CCG level and annual savings available for each CCG for the above switches.

Full data pack available here https://pdata.uk/#/views/B199_OxycodoneNaloxone/Bulletindata?:iid=3

Targinact® tablets are licensed for severe pain which can be adequately managed only with opioid analgesics. Trials conducted with Targinact® in patients with moderate to severe non-cancer pain have shown no difference in pain control compared with oxycodone. Targinact® tablets reduced but did not eliminate the need for laxatives. However, the trials did not use regular stool-softening and stimulant laxatives, as is standard practice. There are no published trials comparing oxycodone/naloxone PR tablets against other oral strong opioids given with regular stool-softening and stimulant laxatives, the recommended laxative regimen. Where appropriate Targinact® can be switched to morphine sulfate MR. If a switch to morphine is not appropriate a cost effective branded generic oxycodone preparation should be considered.

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onal Pres P resources

Briefing	Patient leaflets, audit, slideset

Available here: https://www.prescqipp.info/our-resources/bulletins/oxycodonenaloxone-targinact/

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